UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

IN RE: NATIONAL PRESCRIPTION OPIATE LITIGATION	)	MDL No. 2804
_____	)	Case No. 1:17-MD-2804
THIS DOCUMENT RELATES TO ALL CASES	)	Hon. Dan A. Polster

WEDNESDAY, APRIL 24, 2019

HIGHLY CONFIDENTIAL – SUBJECT TO FURTHER CONFIDENTIALITY REVIEW

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Videotaped deposition of Anna Lembke, M.D., held at the offices of Lieff Cabraser Heimann & Bernstein, LLP, 275 Battery Street, 29th floor, San Francisco, California, commencing at 8:07 a.m., on the above date, before Carrie A. Campbell, Registered Diplomate Reporter and Certified Realtime Reporter.

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A. Yes.

Q. Okay. Does the Dependence Effect include within its scope individuals who deliberately misused an opioid medication knowing that they were not using it for its intended indication; for example, crushing it, snorting it for a high, for euphoria, instead of to treat an indicated pain condition?

A. Yes.

Q. So the third of your triagrid {phonetic} is the Gateway Effect, capital G, capital E.

So in -- on page 86 of your report, Exhibit 1, you describe the Gateway Effect as -- you say, "The trajectory to addiction begins with exposure." Is that right?

A. That's right.

Q. Okay. So have you ever tested -- well -- actually, strike that.

I wanted to ask one more question about the Dependence Effect.

Have you ever published the theory of the Dependence Effect in any

if I've personally done that quantitative research?

QUESTIONS BY MR. TSAI:

Q. Yes.

A. I have not.

Q. Have you ever used the specific terminology of the Gateway Effect and published that observation in any peer-reviewed scientific journal?

A. No.

Q. Have you ever tested the Gateway Effect phenomenon to rule out the inclusion of individuals who deliberately committed a crime in obtaining and using opioids?

A. I wouldn't rule out those individuals.

Q. Okay. So the Gateway Effect, as you envision it, as you define it, does include within its scope persons, including persons in Cuyahoga and Summit County, who deliberately committed a crime in obtaining and using opioids?

A. Yes.

Q. Does the Gateway Effect include

within its scope individuals who deliberately misused a prescription opioid medication knowing that medication was not prescribed to them?

A. Yes.

Q. Does the Gateway Effect include within its scope individuals who deliberately misused a prescription opioid medication knowing it -- knowing that they were using it contrary to its intended indication and approved indication, for example, to get a high instead of treating pain?

A. So I would like to go back and amend what I said previously about the Gateway Effect and refer to my report, which on page 86, specifically says that the Gateway Effect describes those individuals who became exposed and addicted, including individuals who turned from prescription opioids to illicit sources of opioids such as heroin.

So what I'm -- the group I'm referring to in the Gateway Effect is, in fact, those individuals who started with a medical prescription and then became addicted

through that medical prescription, as distinct from the Tsunami Effect, which is those individuals who -- which includes those individuals who used an opioid not necessarily prescribed to them.

Q. Okay. So the -- you know, the beginning bound of the set of individuals that you define as within the Gateway Effect are those individuals who received a prescription directly from a doctor?

A. Yes, and thank you for allowing me the opportunity to clarify that.

Q. So the Gateway theory posits a particular direction of events: First, prescription opioids prescribed by a doctor, and then later illegal heroin or street fentanyl addiction; is that right?

A. Not necessarily.

So that individual -- so you're right in the sense that it posits an individual who began with a prescription of an opioid from a doctor, but it -- and it could include those individuals who then turn to illicit sources of heroin, but it also includes those individuals who become

addicted in an ongoing matter -- manner using the opioids prescribed by that doctor.

Q. Have you ever tested whether the Gateway Effect is confounded by individuals who had already used heroin before prescription opioid medications?

MR. ARBITBLIT: Object to form.

THE WITNESS: Well, that's something that the McCabe article looked at, and I think one of the salient findings there is it's really the combined effect of access to nonmedical opioids, plus medical use, that confers risk. It's not one or the other in isolation, and both of those individual groups can become addicted.

So people can get addicted entirely through a medical prescription and not engage in nonmedical use. They can engage in nonmedical use and then also be exposed medically; thus compounding their risk.

inform that problem.

Furthermore, we know that many people without a past history of addiction can get addicted to opioids through a doctor's prescription.

QUESTIONS BY MR. TSAI:

Q. Okay. And since your opinion isn't -- individual's personal history of substance use disorder is not information that you would need to know, you did not review any such information for any actual individual with opioid use disorder in Cuyahoga and Summit County; am I right?

MR. ARBITBLIT: Object to form. Object to the preface.

THE WITNESS: I did not review any individual patient's history.

QUESTIONS BY MR. TSAI:

Q. So based upon your clinical experience, can you walk us through the steps between a person receiving a prescription from a doctor for an opioid medication and the ultimate outcome of going out to a street dealer and seeking illegal, nonprescribed, nonregulated heroin or fentanyl?

How does that -- how does the Gateway Effect play out in your mind from prescription to going out into a street dealer?

MR. ARBITBLIT: Object to form. Vague. Compound.

THE WITNESS: An individual presents in a medical clinic with pain and is prescribed opioids by that doctor.

The doctor has been misled by false promotional statements on the part of defendants to believe that there are benefits to the use of opioids used long term in the treatment of pain, despite the absence of evidence for that. And that doctor has also been told that the risks are very small for addiction as long as that individual is being prescribed opioids for a pain condition.

So that well-intentioned and compassionate doctor, who is trying to do the right thing, will continue that opioid prescription and even increase

the dose over time as that patient inevitably develops tolerance.

That doctor, furthermore, having been misled by the defendants to believe that no dose is too high, will continue to escalate that dose over months to years until that patient is at dangerously high doses of opioids and at risk for all kinds of morbidity and mortality, including the risk of addiction.

And eventually that individual, who is on very high doses of opioids, has neurologic changes in their brain such that if they -- they begin to experience withdrawal often between doses, so intradose withdrawal.

They have the sensation that was validated by their doctor, but which is probably not the case, that the -- they need the opioids to treat their pain when, in fact, taking the opioids is most likely just treating withdrawal from the last dose, but the physiology and the pain of withdrawal

drives that individual to then become very preoccupied with their pain, very preoccupied with the opioids, spending more and more time at the doctor's office with pain complaints, reporting that the opioids are no longer working, because they don't work in most cases for chronic pain.

And again, the compassionate doctor, being told that no dose is too high, continues to escalate until that individual is at a very, very high dose, and that individual spends almost all of their time possibly going to the emergency room to try to get more opioids to help with their worsened pain and their withdrawal and their tolerance, to the point that that individual has developed a full-blown opioid addiction within the context of medical care.

Now, should it happen that at some point that doctor retires or that doctor gets ill and can't treat that person anymore or that individual

moves to another region or the doctor moves to another region and then that individual can no longer obtain the opioids through the prescription of that -- of that doctor, then sometimes individuals will look to alternative and illicit sources of opioids. And to their mind -- in their mind, they are treating their pain when they have also developed an opioid use disorder.

QUESTIONS BY MR. TSAI:

Q. Do you agree with -- let me know if you agree or disagree with this.

When individuals become addicted to an opioid, they remain human beings?

A. Of course I agree with that.

Q. And true or false, an opioid-addicted person is just a mindless zombie?

MR. ARBITBLIT: Object to form.

THE WITNESS: I don't even know how -- that's really offensive, and I don't even know how to respond to that.

prescription opioid users that then turn to heroin use.

Do you see that?

A. Uh-huh.

Q. And they also cite the Jones study, which has a similarly low number, 4.2 percent, of persons who had used prescription opioids nonmedically then turn to heroin use.

Do you see that?

A. (No response.)

Q. And do you have any basis to disagree with those data?

A. I'm not disagreeing with those data, but I think it would be important to look at actual numbers, not just percentages, because when looking at actual numbers of people who are using opioids nonmedically who progress to heroin use, it gets to be very high numbers.

Q. Okay. And Compton talks about the aggregate big picture. So at the very bottom of that same paragraph, the NEJM article states, "Yet taken in total, the available data suggests that nonmedical

prescription opioid use is neither necessary nor sufficient for the initiation of heroin use and that other factors are contributing to the increase in the rate of heroin use and related mortality."

Do you agree with that statement?

MR. ARBITBLIT: Object to form.

THE WITNESS: I would say that I agree that it's neither necessary nor sufficient, but it has been a huge factor in the last two decades, three decades, among individuals who use heroin as evidenced by survey studies showing that 80 percent of people who use heroin began with a prescription opioid.

QUESTIONS BY MR. TSAI:

Q. And they use that nonmedically, that figure?

MR. ARBITBLIT: Object to form.

QUESTIONS BY MR. TSAI:

Q. Correct?

A. Let me look at that.

My reading of that article is